K090681

5. 510(k) Summary

AUG 12 2009

TransCu O_2

Date of Summary	06/29/09
Submitter/Contact Person	H. Carl Jenkins The **Wood Burditt** Group 10 E. Scranton Ave., Suite 201 (ph) (847) 234-7500 x 205 (fax) (847) 574-0728 (email) hcjenkins@woodburditt.com
Applicant	Electrochemical Oxygen Concepts, Inc 2 Amber Glen San Antonio, TX 78257
Device Name	TransCu O_2
Common Name	Low Dose Tissue Oxygenation System (classified as a "Topical Oxygen Chamber for Extremities" device type)
Classification	"Topical Oxygen Chamber for Extremities" Regulation Number: 21 CFR §878.5650 Product Code: KPJ Panel Code: General and Plastic Surgery Device Class: III (proposed as Class II (71 FR 17390)).
Legally Marketed Predicate Devices	The TransCu O_2 is substantially equivalent in respect to the intended use, design and method of operation to: Name: OxyBox System 510(k) number: K023456 Manufacturer: OxyFast Corporation
Device Description	TransCu O2 is a low dose tissue oxygenation system for the treatment of wounds such as venous leg ulcers, diabetic foot ulcers and pressure ulcers. TransCu O2 is intended for use with wound

	dressings. TransCu O2 consists of a handheld electrochemical oxygen concentrator, an oxygen delivery extension set and a wound site oxygen delivery cannula. The TransCu O2 device incorporates enhanced fuel cell chemistry, utilizing a Proton Exchange Membrane to electrochemically generate the low dose pure oxygen. The battery operated device is lightweight, portable and can be worn discretely, functioning in remote communication with the wound site through long microbore tubing. TransCu O2 extracts oxygen from room air; concentrates the oxygen through the PEM; and then creates an oxygen rich environment by increasing the available oxygen at the wound site under the dressing.
Intended Use and Indications	The TransCu O_2 low dose tissue oxygenation system is intended for use with wound dressings to treat the following: • Skin ulcerations due to diabetes, venous stasis, post surgical infections and gangrenous lesions • Pressure ulcers • Infected residual limbs • Skin grafts • Burns • Frostbite
Performance Testing	Bench testing validates that the TransCu O_2 performs according to its specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

The Wood Burditt Group
% Mr. H. Carl Jenkins
10 E. Scranton Avenue, Suite 201
Lake Bluff, Illinois 60044

AUG 12 2009

Re: K090681
Trade/Device Name: TransCu O_2
Regulation Number: 21 CFR 878.5650
Regulation Name: Topical oxygen chamber for extremities
Regulatory Class: Class III
Product Code: KPJ
Dated: July 6, 2009
Received: July 7, 2009

Dear Mr. Jenkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090681

Device Name: TransCu O_2

Indications for Use:

The TransCu O_2 low dose tissue oxygenation system is intended for use with wound dressings to treat the following:

- Skin ulcerations due to diabetes, venous stasis, post surgical infections and gangrenous lesions
- Pressure ulcers
- Infected residual limbs
- Skin grafts
- Burns
- Frostbite

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MKay

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090681